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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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<i>'</i>	Complete if Known
Application Number	10/600,997
Filing Date	June 20, 2003
First Named Inventor	ALLISON, James P.
Art Unit	1653-1644
Examiner Name	To Be Assigned I. OUS PENSK
Attorney Docket Number	A-71608/TA1 /DHR (465174-00460)

U.S. PATENT DOCUMENTS							
Examiner bitials*	Cite No.1	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
	A1	2002/0071839 A1	06-13-2002	Collins et al.			

		,	OREIGN PATEN	IT DOCUMENTS		
Examiner Initials*	Cite No.1	Foreign Patent Document Country Code <sup>2</sup> Number <sup>2</sup> Kind Code <sup>5</sup> (if known)	Publication Cate MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
0.0	B1 *	WO 99/40100 A1	08-12-1999	Human Genome Sciences, Inc.		
	B2 *	WO 02/072794 A2	09-19-2002	Incyte Genomics, Inc.		
	В3	WO 04/000221 A2	12-31-2003	The Regents of the University of California		
	B4	WO 02/06317 A2	01-24-2002	Corixa Corp.		
	B5	WO 02/10187 A1	02-07-2002	Mayo Foundation for Medical Education and Research	/	
	B6	WO 02/02624 A2	01-10-2002	Amgen, Inc.		
	B7	WO 02/16581 A2	02-28-2002	Genentech, Inc.		
	B8	WO 02/16429 A2 .	02-28-2002	Genentech, Inc.	4	

		NON PATENT LITERATURE DOCUMENTS	
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	C1	ABBAS, A.K., et al., "T-cell stimulation: an abundance of B7s," Nat. Med. 5(12):1345-1346 (Dec. 1999).	
	C2	ANDERSON, D., et al., "Paradoxical inhibition of T-cell function in response to CTLA-4 blockade; heterogeneity within the human T-cell population," Nat. Med. 6(2):211-214 (Feb. 2000).	
	C3	ARCECI, R., "The potential for antitumor vaccination in acute myelogenous leukemia," J. Mol. Med. 76:80-93 (1998).	
	C4	BODEY, B., et al., "Failure of cancer vaccines: the significant limitations of this approach to immunotherapy," Anticancer Res. 20(4):2665-2676 (Jul. – Aug. 2000).	
	C5	BRODIE, D., et al., "LICOS, a primordial costimulatory ligand," Curr. Biol. 10(6):333-336 (Mar. 2000).	
	C6	CARRENO, B.M., et al., "The B7 family of ligands and its receptors: new pathways for costimulation and inhibition of immune response," Annu. Rev. Immunol. 20:29-53 (2002).	<u>.</u>
	C7	CHAMBERS, C., et al., "CTLA-4-mediated inhibition in regulation of T cell responses: mechanisms and manipulation in tumor immunotherapy," <i>Annu. Rev. Immunol.</i> 19:565-594 (2001).	
	C8	CHAMBERS, C., et al., "Thymocyte development is normal in CTLA-4-deficient mice," Proc. Natl. Acad. Sci. USA 94(17):9296-9301 (Aug. 1997).	
1)	C9	CHAPOVAL, A.I., et al., "B7-H3: a costimulatory molecue for T cell activation and IFN-y production," Nat. Immunol. 2(3):269-274 (Mar. 2001).	
	miner ials*	C1 C2 C3 C4 C5 C6 C7 C8	Cite No.¹ Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.  C1 ABBAS, A.K., et al., "T-cell stimulation: an abundance of B7s," <i>Nat. Med.</i> 5(12):1345-1346 (Dec. 1999).  C2 ANDERSON, D., et al., "Paradoxical inhibition of T-cell function in response to CTLA-4 blockade; heterogeneity within the human T-cell population," <i>Nat. Med.</i> 6(2):211-214 (Feb. 2000).  C3 ARCECI, R., "The potential for antitumor vaccination in acute myelogenous leukemia," <i>J. Mol. Med.</i> 76:80-93 (1998).  C4 BODEY, B., et al., "Failure of cancer vaccines: the significant limitations of this approach to immunotherapy," <i>Anticancer Res.</i> 20(4):2665-2676 (Jul. – Aug. 2000).  C5 BRODIE, D., et al., "LICOS, a primordial costimulatory ligand," <i>Curr. Biol.</i> 10(6):333-336 (Mar. 2000).  C6 CARRENO, B.M., et al., "The B7 family of ligands and its receptors: new pathways for costimulation and inhibition of immune response," <i>Annu. Rev. Immunol.</i> 20:29-53 (2002).  C7 CHAMBERS, C., et al., "CTLA-4-mediated inhibition in regulation of T cell responses: mechanisms and manipulation in tumor immunotherapy," <i>Annu. Rev. Immunol.</i> 19:565-594 (2001).  C8 CHAPOVAL, A.I., et al., "Thymocyte development is normal in CTLA-4-deficient mice," <i>Proc. Natl. Acad. Sci. USA</i> 94(17):9296-9301 (Aug. 1997).

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Examiner Signature	Thia	aspendi	Date Considered	3/	13/	2006

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Complete if Known Substitute for form 1449A/PTO (Modified) 10/600.997 Application Number INFORMATION DISCLOSURE June 20, 2003 Filing Date STATEMENT BY APPLICANT ALLISON, James P. First Named Inventor Art Unit 4653-(use as many sheets as necessary) Examiner Name To Be Assigned A-71608/TAL/DHR (465174-00460) 3 Attorney Docket Number Sheet 2

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.	include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	I.
In	C10	CHRISTADOSS, P., et al., "Animal models of Myasthenia gravis," Clin. Immunol. 94(2):75-87 (Feb. 2000).	
	C11	COYLE, A.J., et al., "The expanding B7 superfamily: increasing complexity in costimulatory signals regulating T-cell function," Nat. Immunol. 2(3):203-209 (Mar. 2001).	
	C12	DAMLE, N., et al., "Costimulation of T lymphocytes with integrin ligands intercellular adhesion molecule-1 or vascular cell adhesion molecule-1 induces functional expression of CTLA-4, a second receptor for B7," <i>J. Immunol.</i> 152:2686-2697 (1994).	
	C13	DONG, H., et al., *B7-H1, a third member of the B7 family, co-stimulates T-cell proliferation and interleukin-10 secretion, *Nat. Med. 5(12):1365-1369 (Dec. 1999).	
	C14	DUDLEY, M.E., et al., "Cancer regression and autoimmunity in patients after clonal repopulation with anti-tumor lymphocytes," Science 268(5594):850-854 (Oct. 2002).	
	C15	EGEN, J.G., et al., "CTLA-4: new insights into its biological function and use in tumor," Nat. Immunol. 3(7):611-618 (Jul. 2002).	<u> </u>
	C16	FREEMAN, G.J., et al., "Engagement of the PD-1 immunoinhibitory receptor by a novel B7 family member leads to negative regulation of lymphocyte activity," <i>J. Exp. Med.</i> 192(7):1027-1034 (Oct. 2000).	
	C17	GAO, P., et al., "Tumor vaccination that enhances antitumor T-cell responses does not inhibit the growth of established tumors even in combination with interleukin-12 treatment: the importance of inducing intratumoral T-cell migration," J. Immunother. 23(6):643-653 (2000).	
	C18	GRIBBEN, G., et al., "Alloantigen and concomitant CTLA4 signaling induces clonal deletion of alloreative T cells: a novel method to prevent GVHD," <i>Blood</i> 84(10):397a (1994).	
	C19	HESLOP, H., "Cytokine gene transfer in the therapy of malignancy," Baillière Clin. Haematol. 7(1):135-151 (Mar. 1994).	
	C20	KEARNEY, E., et al., "Antigen-dependent clonal expansion of a trace population of antigen-specific CD4+ T cells in vivo is dependent on CD28 costimulation and inhibited by CTLA-4," J. Immunol. 155(3):1032-1036 (Aug .1995).	
	C21	KRUMMEL, M., et al., "Superantigen responses and co-stimulation: CD28 and CTLA-4 have opposing effects on T cell expansion in vitro and in vivo," J. Exp. Med. 182(2):459-465 (Aug. 1996).	
	C22	LATCHMAN, Y., et al., "PD-L2 is a second ligand for PD-1 and inhibits T cell activation," Nat. Immunol. 2(3):261-268 (Mar. 2001).	
	C23	LEACH, D., et al., "Enhancement of antitumor immunity by CTLA-4 blockade," Science 271(5256):1734-1739 (Mar. 1996).	
	C24	LEE, KH., et al., "Increased vaccine-specific T cell frequency after peptide-based vaccination correlates with increased susceptibility to <i>in vitro</i> stimulation but does not lead to tumor regression," <i>J. Immunol.</i> 163(11):6292-6300 (Dec. 1999).	
	C25	LEWIS, G., et al., "Growth regulation of human breast and ovarian tumor cells by heregulin: evidence of the requirement of ErbB2 as a critical component in mediating heregulin responsiveness," <i>Cancer Res.</i> 56:1457-1465 (Mar. 1996).	
	C26	LIANG, P., et al., "The right place at the right time: novel B7 family members regulate effector T-cell responses," Curr. Opin. Immunol. 14(3):384-390 (Jun. 2002).	
	C27	LING, V., et al., "Cutting Edge: Identification of GL50, a novel B7-like protein that functionally binds to ICOS receptor," J. Immunol. 164(4):1653-1657 (Feb. 2000).	
In	C28	NISHIMURA, H., et al., "PD-1: an inhibitory immunoreceptor involved in peripheral tolerance," <i>Trends Biotechnol.</i> 22(5):265-268 (May 2001).	

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1.0	C29	PARDOLL, D.M., et al., "Tumor reactive T cells get a boost," Nat. Biotechnol. 20(12):1207-1208 (Dec. 2002).	
	C30	SOTOMAYOR, E., et al., "In vivo blockade of CTLA-4 enhances the priming of responsive T cells but fails to prevent to induction of tumor antigen-specific tolerance," Proc. Natl. Acad. Sci. USA 96(20):11476-11481 (Sep. 1999).	
	C31	SUN, M., et al., "Characterization of mouse and human B7-H3 genes," J. Immunol. 168(12):6294-6297 (Jun. 2002).	
	C32	SUSSMAN, J., et al., "Activation of T lymphocytes for the adoptive immunotherapy of cancer," Ann. Surg. Oncol. 1(4):296-306 (Jul. 1994).	
	C33	SWALLOW, M.M., et al., "B7h, a novel costimulatory homolog of B7.1 and B7.2, is induced by TNFa," Immunity 11(4):423-432 (Oct. 1999).	
	C34	TIMMERMAN, J., et al., "Dendritic cell vaccines for cancer immunotherapy," Annu. Rev. Med. 50:507-529 (1999).	
	C35	TRIOZZI, P., et al., "Clinical and immunologic effects of a synthetic β-human chorionic gonadotropin vaccine," Int. J. Oncol. 5:1447-1453 (1994).	$oxed_{-}$
	C36	TSENG, S.Y., et al., "B7-DC, a new dendritic cell molecule with potent costimulatory properties for T cells," J. Exp. Med. 193(7):839-846 (Apr. 2001).	
	C37	WALLACK, M., et al., "Active specific immunotherapy with vaccinia melanoma oncolysate," <i>Immunity</i> 1(5):405-413 (Aug. 1994).	
	C38	WANG, S., et al., "Costimulation of T cells by B7-H2, a B7-like molecule that binds ICOS," Blood 96(8):2808-2813 (Oct. 2000).	
	C39	YANG, Y., et al., "Enhanced induction of antitumor T-cell by cytotoxic T lymphocyte-associated molecule-4 blockade: The effect is manifested only at the restricted tumor-bearing stages," Cancer Res. 57:4036-4041 (Sep. 1997).	
	C40	YOSHINAGA, S.K., et al., "T-cell ∞-stimulation through B7RP-1 and ICOS," Nature 402(6763):827-832 (Dec. 1999).	
	C41	ZAKS, T., et al., "Immunization with a peptide epitope (p369-377) from HER-2/neu leads to peptide-specific cytotoxic T lymphocytes that fail to recognize HER-2/neu+ tumors," Cancer Res. 58:4902-4908 (Nov. 1998).	
10	C42	ZHU, J., et al., "Cytotoxic T lymphocyte-associated antigen 4 (CTLA-4) blockade enhances incidence and severity of experimental autoimmune neuritis in resistant mice," J. Neuroimmunol. 115(1-2):111-117 (Apr. 1999).	

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